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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,049	10/21/2003	Tomohiro Kono	038779/270668	3500

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/690,049

Applicant(s)

KONO ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 7-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

This application filed October 21, 2003, claim priority to 2002-0064202, filed October 21, 2002 in the REPUBLIC OF KOREA

Applicants' amendment filed July 19, 2006 has been received and entered. Claim 22 has been added. Claims 1-22 are pending.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on July 19, 2006 is acknowledged. The traversal is on the ground(s) that the methods of groups III and V, use or depend on the method of group I, and should be considered together. This is not found persuasive because neither of groups III or V depend on claim 1, nor require the using electrical stimulation to synchronize the culture. Groups III and V would not require the search needed for group I, nor would a search of groups III and V provide relevant art for group I.

Newly added claim 22 depends on claim 3, and simply sets forth membrane antigen makers. Claim 22 is drawn to the method of group I, and will be examined with group I.

It is noted that the Examiner had required restriction between product and process claims, and that process claims have been elected, not product claims which would be subject to rejoinder.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-22 are pending. Claims 7-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no

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allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 19, 2006. Claims 1-6 and 22, drawn to a method for preparing a donor cell for nuclear transfer comprising applying electrical stimulation to donor cells and culturing synchronously to metaphase stage are currently under examination.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on October 22, 2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because there is no translation to access the claim of priority to the claimed subject matter. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is

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advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Objections

Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In this case, a specific method directed to the intended use appears to have no weight on the breadth of practicing claim 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claim 1 is unclear to the relationship of steps (a) and (b). It is unclear if the electrical stimulation is supposed to result in synchronization or if they are two unrelated broad separate

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steps for treating a cell. The claims are vague and unclear, and appear to be incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. In this case, the omitted elements are conditions where (a) results in (b).

Claim 2 is vague and unclear in the recitation of various values at which the cells are treated. With respect to the voltage it is unclear how this is calculated or provided (i.e. /cm, total,...), values of condenser or resistance are also relative to how they are calculated or provided. It appears in part that the recitations support settings on a particular machine or circumstances.

Claims 3 and 22 lack sufficient antecedent basis for the method steps since claim 1 does not require any particulars to the cell type used, it encompasses differentiated and undifferentiated cells, to support the limitation in the claim for using markers of undifferentiated cells. The claims appear to be incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amano *et al.* (J Exp Zoo 289:139-145 (2001)), Bronson *et al.* (PNAS 93:9067-9072 (1996)) and Wallace *et al.* (NAR 28(6):1455-1464 (2000)).

Amano *et al.* teach methods of nuclear transfer to produce cloned mice. Amano *et al.* teach the use of cultures of mouse embryonic stem cells that have synchronized into metaphase by the use of nocodazole (see summary in abstract). Amano *et al.* teach that ES cells serve as a means to easily manipulate the genome of the mouse *in vitro* (first column), however does not provide any specific methodology for this known in the art at the time of filing. Both Bronson *et al.* and Wallace *et al.* provide methods known in the art at the time of filing for altering the genome of a mouse by manipulating a mouse ES cell by inserting a DNA construct. More specifically, Bronson *et al.* and Wallace *et al.* teach methods of providing a DNA construct and electroporating the construct into the cell, wherein homologous recombination allows for site specific insertion of the DAN construct. Both Bronson *et al.* and Wallace *et al.* provide for the initial step of applying an electrical stimulation to ES cells, while Amano *et al.* provides for methods of using the ES cells synchronized in metaphase to produce a transgenic mouse, and therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the methods of Amano *et al.* with the methods of Bronson *et al.* and Wallace *et al.* in order to provide a large number of cloned mice from a single starting ES

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cell. One having ordinary skill in the art would have been motivated to combine the methods in order to provide multiple cloned mice from the ES cell obtained by the methods of Bronson *et al.* and Wallace *et al.* There would have been a reasonable expectation of success given the successful results of all of Bronson *et al.*, Wallace *et al.* and Amano *et al.* of the methods practiced in part.

It is noted the specification provides specific working examples and tables with results (page 14) which indicate a difference between mouse ES cells that have and have not received electrical stimulation, however it is unclear if this affect is commensurate in scope with the breadth of the claims. If there is some unexpected result, in particular with respect to using mouse ES cells it is noted that reliance upon inherency is not improper even though rejection is based on Section 103 instead of Section 102. *In re Skoner*, et al. 186 USPQ 80 (CCPA). In this case introducing a transgene by electroporation provides any potential benefit that electrical stimulation would/could provide.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over as applied to claims 1, 4-6 above, and further in view of Canatella *et al.* (Gene Ther 8:1464-1469 (2001)) and Canatella *et al.* (Biophysical J 80:755-764 (2001)).

Bronson *et al.*, Wallace *et al.* and Amano *et al.* are discussed above. Briefly, Bronson *et al.* and Wallace *et al.* provide for the initial step of applying an electrical stimulation to ES cells, while Amano *et al.* provides for methods of using the ES cells synchronized in metaphase to produce a transgenic mouse. However, the methods of Bronson *et al.* and Wallace *et al.* teach various conditions, but do not teach an electrical stimulation that is specifically recited in claim 2

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(see and compare Bronson *et al.* page 9068, and Wallace *et al.* page 1456, second column). Both of the references of Canatella *et al.* provide detailed guidance for the affects of multiple parameters for the optimization of electroporation of DNA into a cell. By optimizing the parameters such as volatage and time of pulse, Canatella *et al.* teach that one can reduce among various affects cell death and degree of DNA uptake. Canatella *et al.* teach varying multiple parameters and that various conditions and cell types demonstrate significant differences. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the methods of optimization taught by Canatella *et al.* in the method of Bronson *et al.* and Wallace *et al.* to more effectively deliver DNA constructs to mouse ES cells. One having ordinary skill in the art would have been motivated to optimize the uptake of DNA by the ES cells to increase the efficiency of DNA uptake and reduce cell death. There would have been a reasonable expectation of success given the already successful results of Bronson *et al.* and Wallace *et al.* to optimize the methods with the guidance provided by Canatella *et al.*

Thus, the claimed invention as a whole was clearly *prima facie* obvious.

Conclusion

No claim is allowed.

Claims 3 and 22 are free of the art of record because method of using ES cells or more generally undifferentiated cells presumes the presence of such cells, and would fail to provide any motivation for isolating such cells after electrostimulation. To the contrary, the methods of

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electroporation of ES cells all focus on screening and identifying a clone in culture at best by physical morphology of the ES cell.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

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AU 1632